DEPARTMENT OF HEALTH & HUMAN SERVICES M 884N

Public Health Service

Food and Drug Administration
Minneapolis District
240 Hennepin Avenue
Minneapolis MN 55401-1999
Telephone: 612-334-4100

PURGED FOI

May 6, 1997

cc: HFI-35/FOI Staff
DWA

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Refer to MIN 97 - 44

Henrik M. Nielsen
President
Bernafon-Maico, Inc.
9675 W. 76th Street
Eden Prairie, Minnesota 55344

Dear Mr. Nielsen:

We are writing to you because on April 14-16, 1997, an investigator from the Food and Drug Administration (FDA) collected information that revealed a serious regulatory problem involving products known as Maico MA-39, MA-40, and MA-41 portable audiometers which are made and marketed by your firm.

Under a United States Federal law, the Federal Food, Drug, and Cosmetic Act (the Act), these products are considered to be medical devices because they are used to diagnose or treat a medical condition or to affect the structure or function of the body. Audiometers are medical devices as defined by Section 201(h) of the Act.

The law requires that manufacturers of medical devices adhere to Current Good Manufacturing Practice (CGMP) regulations for Medical Devices as specified in Title 21, Code of Federal Regulations (CFR), Part 820 in the methods used in, facilities or controls used for manufacturing, packing, storage, or installation of medical devices.

Our inspection found your products are in violation of the law because:

1. There are no written procedures to identify quality assurance problems reported in complaints and repair requests [21 CFR Part 820.20 (a)(3)].

2. The system for screening repair and service requests fails to identify complaints. Additionally, complaints and failures are not always investigated (21 CFR Parts 820.198 and 820.162).

3. Software revisions have been made without Engineering Change Order (ECO) control, resulting in the distribution of audiometers with unapproved software. ECOs do not include a record of software source code changes and obsolete versions are not archived [21 CFR Part 820.100 (a)(2)]. Software source code is not controlled under the document control system (21 CFR Part 820.80).

In legal terms, the products are adulterated under Section 501(h) of the Act.

The specific violations noted in this letter and in the FDA-483 issued at the close-out of the inspection (copy enclosed) may be symptomatic of serious underlying problems in your firm's manufacturing and quality assurance systems. You are responsible for investigating and determining the causes of the violations identified by the FDA. If the causes are determined to be systems problems, you must promptly initiate permanent corrective actions.

It should be noted that the items regarding software documentation and change, inadequate failure investigations; and identification of complaints when screening repair and service requests were cited on the form FDA-483, Inspectional Observations, that was issued at the close of the previous inspection of your firm on April 24, 1995. Your Engineering Manager, Scott Savre, participated in the discussions of the items on both the previous and current FDA-483s.

Thank you for your April 29, 1997, response to our FDA-483, Inspectional Observations form, dated April 14, 1997.

Your responses to the concerns referenced in the FDA-483 are noted and are being made part of the official file. The corrective actions that you are taking are appropriate for addressing most of the concerns raised during the April 1997 inspection. However, your response does not address the issue of lack of validation for changes that have already been made to the software (item #5 on the FDA-483). During the next inspection, we will assess the effectiveness of the implementation of the corrective measures that you reference in your letter.

This letter is not intended to be an all-inclusive list of deficiencies at your facility. As president, the most responsible individual at Bernafon-Maico, Inc., it is ultimately your responsibility to ensure that devices manufactured in your facility in Eden Prairie, MN, are in compliance with each requirement of the Act and regulations.

You should know that this serious violation of the law may result in FDA taking regulatory action without further notice to you. These actions include, but are not limited to, seizing your product inventory, obtaining a court injunction against further marketing of the product, or assessing civil money penalties. Also, other Federal agencies are informed about the Warning Letters we issue, such as this one, so that they may consider this information when awarding government contracts. Additionally, no pending applications for pre-market approval (PMAs) or export approval requests will be approved, and no pre-market notifications (Section 510(k)'s) will be found to be substantially equivalent for products manufactured for your facility until the violations have been corrected.

It is necessary for you to take action on this matter now. Please let this office know in writing within 15 working days from the date you received this letter of the steps you are taking to correct the problem. We also ask that you explain how you plan to prevent this from happening again. If you need more time, let us know why and when you expect to complete your correction. Please direct your response to Compliance Officer Howard E. Manresa at the address indicated on the letterhead..

Finally, you should understand that there are many FDA requirements pertaining to the manufacture and marketing of medical devices. This letter pertains only to the issue of Current Good Manufacturing Practices for your devices and does not

necessarily address other obligations you have under the law. You may obtain general information about all of FDA's requirements for manufacturers of medical devices by contacting our Division of Small Manufacturers Assistance at 1-800-638-2041 or through the Internet at http://www.fda.gov.

If you have more specific questions about how FDA marketing requirements affect your particular device, or about the content of this letter, please feel free to contact Mr. Manresa at (612)334-4100 ext. 156.

Sincerely yours,

John Feldman
Director
Minneapolis District

HEM/ccl

Enclosures: FDA-483, 4/16/97